aqueous formulation, which can be conveniently diluted, for example, in the drinking water of a vertebrate. Pharmacologically and biologically active compounds that are water insoluble or water labile may also be administered using this method Water labile compounds are found to retain their stability in aqueous solutions for at least 10 days (specification, page 5, line 6), and water insoluble compounds may be administered in aqueous solutions according to the present invention. The present claims have been amended to more clearly describe the invention as a non-aqueous formulation, and not for purposes of patentability.

Claims 1-51 stand rejected as allegedly being obvious over Lo in combination with Macy and Jon. This rejection is respectfully traversed.

While Lo describes a composition containing an active compound, a polyol, benzyl alcohol, and an emulsifier, he specifically states water is an essential component. Thus, Lo describes an aqueous formulation whereas the present invention provides a non-aqueous formulation. Lo explains that his formulation is an aqueous formulation at line 36, stating at Col. 2, "The instant invention resides in the unexpected stabilization of an aqueous solution of ivermectin or other avermectin compound prepared from water and a surface active agent." Lo also describes that his formulation "avoids all of the disadvantages of non-aqueous formulations while retaining the required attributes of a parenteral or oral formulation." (Col. 4, lines 6-9). The present invention is a non-aqueous formulation. Thus, Lo teaches away from the use of non-aqueous formulations to avoid their disadvantages, stating that non-aqueous formulations "cause irritation and tissue damage at the injection site, have higher viscosity and poorer syringability; and generally have a higher cost." (Col. 1, lines 22-26).

Jon[1] also describes an aqueous formulation, stating "it is an object of this invention to provide a stabilized, water-based mini-emulsion of a hydrolyzable, biologically active aza compound..." (Col. 2, lines 16-19).

[1] The Examiner refers to "Benning" in the text of the Office Action, but it is believed the Examiner meant to refer to the Jon reference. Thus, the Applicant answers assuming the Examiner meant to refer to Jon.

Non-aqueous formulations have advantages over aqueous formulations. For example, concentrated, non-aqueous formulations may be diluted into the drinking water of the treated animals, and dosages easily calculated based on the water consumption of the animal.

While Macy discloses a non-aqueous formulation, the composition of Macy does not contain an emulsifier or benzyl alcohol. A prima facie case of obviousness requires that there be a suggestion or motivation, whether in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. MPEP 2142. Hindsight reasoning is not permitted. MPEP 2145.X. No motivation is provided by Macy, Lo, or Jon for combining these references. That both compositions may be administered to animals by injection or by oral administration does not provide a motivation to combine the references as no benefit to be obtained is taught by either reference. Because Lo and Jon describe aqueous formulations and Macy describes a non-aqueous formulation, the person of ordinary skill in the art would not expect the combination of their ingredients to yield any benefit. In fact, both Lo and Jon lead the person of ordinary skill away from the use of a non-aqueous composition, which further indicates the nonobviousness of the presently claimed invention over these references. MPEP 2141.02; *W.L. Gore & Associates, Inc. v. Garlock, Inc.* 220 USPQ 303 (Fed. Cir. 1983), *cert denied*, 469 U.S. 851 (1984). Therefore, the presently claimed invention is not obvious over Lo, Jon, and Macy.

Atty. Dkt. No. 051091-0401

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date December 17, 2001

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Marked up Copy of Claims

1. (Amended) A [non-aqueous] composition comprising:

an emulsifier;

a polyol;

benzyl alcohol; and

a pharmacologically or biologically active compound;

wherein the composition is provided as a stable, non-aqueous formulation.

17. (Amended) A method of administering a pharmacologically active compound to a vertebrate, comprising:

providing the pharmacologically active compound in the form of a stable non-aqueous formulation [which further comprises] comprising:

an emulsifier;

benzyl alcohol; and

a polyol; and

[diluting] administering the formulation in [an aqueous solution; and

administering the compound in] the drinking water of the vertebrate.

26. (Amended) A method of administering a pharmacologically active compound to a vertebrate, comprising:

providing the pharmacologically active compound in the form of a stable non-aqueous formulation comprising:

an emulsifier;

benzyl alcohol; and

n-methyl pyrrolidone; and

[diluting] administering the formulation in [an aqueous solution; and

administering the compound in] the drinking water of the vertebrate.

45. (Amended) A [non-aqueous] composition comprising:

an emulsifier;

a polyol;

a monohydric alcohol; and

a pharmacologically or biologically active compound;

wherein the composition is provided as a stable non-aqueous formulation.